REMARKS

I. STATUS OF THE CLAIMS

Claims 14 and 34-47 were pending at the time of the final Action dated October 9, 2007. Claims 1-13, 15-34, and 44-47 have been canceled. Claims 14 and 35-43 are amended. The amendments to the claims are mostly of an editorial nature. In essence, Applicants have introduced the subject matter of claims 46 and 47 into claim 14. The amendment to claim 35 removes a recitation objected to by the Examiner and those to claims 36-44 are of editorial nature only, aimed at further clarifying the claimed subject matter. Thus, no new matter has been added by the present response. Claims 14 and 35-43 are currently pending.

Reconsideration in view of the following remarks and entry of the foregoing amendments are respectfully requested.

II. REJECTIONS UNDER 35 U.S.C. §112,FIRST PARAGRAPH

The Action rejects (A) claims 14, 34, 36-41, 43 and 44 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirements, (B) claims 14, 34, 36-41, 43 and 44 under 35 U.S.C. § 112, first paragraph for allegedly not enabling a skilled artisan to make and use the invention commensurate in scope with the claims, and (C) claims 14, 34, 36-41, 43 and 44 under 35 U.S.C. §112 as containing new matter and lacking written description.

A. Claims 14, 36-41 and 43 satisfy the written description requirement

The rejection is moot in light of the amendment of claim 14, which includes deleting the phrase referring to percentage identity, and the cancellation of claims 34 and 44.

B. Claims 14, 36-41 and 43 satisfy the enablment requirement

The Action rejects claims 14, 34, 36-41, 43, and 44 under 35 U.S.C. §112 first paragraph as lacking enablement.

The Examiner's rejection At page 7 of the Action, to the effect that "the predictable correlation between *in vitro* data…and *in vivo* pharmaceutical effects in patients with IGE

has not been established" has been rendered moot by the cancellation of the claim. In view of advancing the prosecution, the Applicant has also amended claim 35 to remove the recitation linking the compound to epilepsy. Applicant wishes to state this deletion and cancellation should not be construed as an admission that claims 34 and 35, as previously drafted, were not enabled. Applicant reserves the right to prosecute this deleted subject matter in further applications.

At the bottom of page 9 of the Action, relating to the enablement rejection, the Examiner states that "while being enabling for assaying sodium channels using protein with full length SCN3A protein of SEQ ID NO: 67 or the ion channel encoded by the nucleic acid of SEQ ID NO:65, as well as a method of selecting a compound using *in vitro* cell based ion channel assay, does not reasonably provide enablement for using any other protein fragments of SEQ ID NO:67 or variants of proteins..., as well as any assays for selecting a compound that can be used for treating IGE". In view of the above-mentioned amendments to the claims, it is respectfully submitted that this rejection has been overcome, since the claims no longer recite any protein fragment of alpha subunit of SCN3A protein and that the claims are now limited to identified SCN3A mutants.

Furthermore, it is well settled that "The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available in the public." MPEP 2164.05(a) (citing *inter alia*, *In re Buchner*, 929 F.2d 660, 661, 18 U.S.P.Q. 2d 1331, 1332 (Fed. Cir. 1991)). The specification describes the use of screening assays for compounds that modulate the biological activity of a sodium channel (page 5, lines 8-25 and page 19, line 20 to page 20, line19). Sodium channel assays were routine in the art and one of skill in the art would be able to use these activity assays as described in the specification. For example, such assays are described in Example 6 and Example 7 of the specification, starting on page 54 and page 57, respectively. The specification on page 55 starting on line 26 reads "In view of proving that D188V in SCN1A [] is a pathogenic mutation [] RNA was isolated from mutant and wildtype clones, and injected into oocytes in view of recording sodium currents by the patch-clamp technique." Also, the specification on page 58 starting at line 3 reads "One particularly preferred functional assay involves the use of Xenopus oocytes and recombinant constructs harboring

normal or mutant sequences of SCN1A, SCN2A, or SCN3A. Xenopus oocytes have been used in functional assays to dissect the structure-function relationship of the cyclic AMP-modulated potassium channel using recombinant KCNQ2 and KCNQ3 (Schroeder *et al.*, 1998)." Furthermore, the concerns expressed by citation to Kohling *et al.*, and Birch *et al.* are considerations that would be dealt with by routine experimentation on the part of one skilled in the art and would not require undue experimentation. Applicants have disclosed at least one method of making and using the claimed invention that bears a reasonable correlation the currently pending claims. Therefore, the pending claims are enabled and satisfy the enablement requirements of 35 U.S.C. §112.

C. Claims 14, 36-41 and 43 does not contain new matter

The Action rejects claims 14, 34, 36-41, 43 and 44 under 35 U.S.C. §112, first paragraph as lacking written description based because of alleged new matter added to the claims.

The rejection is moot in light of the amendment of claim 14 and the cancellation of claims 34 and 44.

In view of the amendments to the claims and of the above and foregoing arguments, the Applicants respectfully request that the Examiner withdraws her rejection of claims 14, and 35 to 44 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description and enablement requirements. Applicants stress that the "Scope of enablement" and written description rejections in the Advisory Action, have been overcome by the amendments to claim 14.

III. REJECTIONS UNDER 35 U.S.C. §112, SECOND PARAGRAPH

The Examiner has rejected claim 36 for using the recitation "the test compound." In view of the amendment of claim 14, which adds "at least one," the antecedent problem noted by the Examiner has been overcome. Claim 36 is thus clear and definite.

IV. REJECTIONS UNDER 35 USC § 102

Claims 14, 34, 37-40, 43 and 44 are rejected as allegedly being anticipated by Clare *et al.*

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP § 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In view of the allegation that Clare *et al.,* is directed to characterization of a sodium channel associated with a "normal" cell then it is implied that any protein being assayed is wildtype. Applicants note that they continue to disagree with the allegation of inherent anticipation set forth during prosecution. In the interest of advancing prosecution Applicants are currently pursuing methods of screening the variants of SCN3A first identified by the Applicants. The current claims are directed to those variants of SCN3A associated with idiopathic generalized epilepsy (IGE). Therefore, Clare *et al.* cannot describe all elements of the current claims. Applicants respectfully request withdrawal of the rejection.

V. REJECTIONS UNDER 35 USC § 103

The Action rejects claims 14, 34, 37-40, 43 and 44 under 35 U.S.C. § 103(a) as being rendered obvious by Clare *et al.,* in view of Hall.

To establish a *prima facie* case of obviousness the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

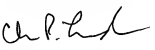
As described above, Clare *et al.* fails to teach all elements of the claimed invention and the Hall reference does not remedy the deficiency of Clare *et al.* Applicants respectfully request the withdrawal of the rejection.

VI. CONCLUSION

In view of the above, it is submitted that the claims are in condition for allowance. Reconsideration and withdrawal of all outstanding rejections are respectfully requested. Allowance of the claims at an early date is solicited. If any points remain that can be

resolved by telephone, the Examiner is invited to contact the undersigned at the telephone number shown below.

Respectfully submitted,



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